

**RECEIVED  
CENTRAL FAX CENTER****JUN 23 2008**Application Number 10/693,005  
Response to Office Action mailed March 21, 2008**REMARKS**

This submission is responsive to the final Office Action dated March 21, 2008. Claims 1-12, 14-21 and 32 are pending.

**Summary of Examiner Interview**

In a telephonic interview initiated by Applicant on June 17, 2008, Applicant's attorneys-of-record, Steven J. Shumaker and Jessica H. Kwak, and Examiners Christopher A. Flory and George Manuel generally discussed the rejection of the claims under 35 U.S.C. § 102(b) based apparently upon a public use or sale of the invention, as presented in the Office Action mailed March 21, 2008. The Office Action alleged that the rejection under 35 U.S.C. § 102(b) was evidenced by the Declaration Under 37 C.F.R. § 1.132 ("Rule 132 Declaration") and Exhibits A-D submitted by Applicant on October 26, 2006. During the telephonic interview, Examiners Flory and Manuel agreed to withdraw the rejection under 35 U.S.C. § 102(b) based upon a public use of the claimed invention.

During the interview, Applicant's attorneys-of-record clarified the purpose of the Rule 132 Declaration. In particular, Applicant's attorneys-of-record noted that the Rule 132 Declaration was filed by Applicant to submit information pursuant to the duty to disclose information that may be material to patentability (37 C.F.R. § 1.56). Applicant's attorneys-of-record noted that the Rule 132 Declaration should not be confused with an affidavit under 37 C.F.R. § 1.131, which is used to overcome a prior art rejection by proving invention of the claimed subject matter by the applicant prior to a particular date.<sup>1</sup>

Examiner Flory clarified that the rejection under 35 U.S.C. § 102(b) was based on an alleged public use of the claimed invention, rather than a sale of the claimed invention. The parties generally agreed that manufacture of the 222 programmers with model number 37731 ("Model 37741 programmers") by Benchmark Electronics does not constitute public use of the claimed invention.

Examiner Flory clarified that the alleged public use was based on the possibility that the remainder of the 222 Model 37741 programmers that were not used for the tests reflected in

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<sup>1</sup> MPEP 2132.

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Exhibits B and C submitted with the Rule 132 Declaration may have been publicly used, as discussed in the Office Action. In particular, the Office Action states that:

It is unclear what range of activities "internal use" [of the remainder of the 222 Model 37741 programmers] could encompass, e.g. whether the controllers [sic] provided to [Medtronic, Inc.] employees might have been allowed to leave secure facilities or to what extent said employees might be allowed to discuss or disclose the nature of the device in a public setting.<sup>2</sup>

Applicant's attorneys-of-record noted that the Rule 132 Declaration establishes that the remainder of the 222 Model 37741 programmers manufactured by Benchmark Electronics that were not used for tests reflected in Exhibits B and D were used internally by employees of Medtronic, Inc. Applicant's attorneys-of-record further noted that the Office Action did not cite to any evidence that establishes that Medtronic, Inc. employees left secure facilities with a Model 37741 programmer or that the employees discussed the Model 37741 programmers in a public setting, as alleged by the Office Action.

In addition, Applicant's attorneys-of-record noted that 35 U.S.C. § 102(b) stated that an invention described in a printed publication, in public use, or on sale more than one year prior to the date of application constitutes a bar to patentability. Neither a Model 37741 programmer leaving "secure facilities" nor discussion or disclosure of the "nature" of the Model 37741 programmer in a "public setting" necessarily establish that Applicant's claimed invention was described in a printed publication, in public use or on sale. Applicant's attorneys-of-record further noted that the Office Action did not provide any dates to establish that the speculated activities occurred more than one year prior to the date of application.

Applicant's attorneys-of-record referred to related applications, such as U.S. Patent Application Serial No. 10/693,007, in which substantially similar Rule 132 Declarations were submitted and considered by the Examiners.

No prior art references were discussed during the telephonic interview and no exhibits were introduced during the interview.

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<sup>2</sup> Office Action dated March 21, 2008 at p. 4, item 4.

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**Claim Rejection Under 35 U.S.C. § 102(b)**

In the final Office Action, claims 1-12, 14-21, and 32 were rejected under 35 U.S.C. § 102(b), based apparently upon a public use of the invention, which the Office Action alleged was evidenced by the Declaration Under 37 C.F.R. § 1.132 ("Rule 132 Declaration") and Exhibits A-D submitted by Applicant on October 26, 2006. Applicant notes that the Office Action referred to the Rule 132 Declaration and Exhibits A-D as being filed on November 2, 2006. However, the documents were filed on October 26, 2006.

Applicant respectfully traverses the rejection. The Office Action fails to establish that the medical device programmer recited in claims 1-12, 14-21, and 32 were in public use more than one year prior to the date of the application for patent in the United States. In support of the rejection of claims 1-12, 14-21, and 32, the Office Action asserted that the 222 programmers manufactured by Benchmark Electronics, Inc. ("Benchmark Electronics") constitute "public" use because Benchmark Electronics is "an external and independent company," and, therefore, the manufacture was a "public" manufacture.<sup>3</sup> As an initial matter, Applicant respectfully traverses the use of a "public manufacture" standard to reject claims 1-12, 14-21, and 32. Section 102(b) of the patent statute refers to "public use" or an "on sale" bar, but makes absolutely no mention of a "public manufacture" standard as being a bar to patentability.

As agreed to between Applicant's attorneys-of-record and Examiners Flory during the telephonic interview on June 17, 2008, the manufacture of the 222 Model 37741 programmers by Benchmark Electronics does not constitute a public use of the claimed invention or a sale under 35 U.S.C. § 102(b).

The information submitted by Applicant by way of the Rule 132 Declaration establishes that the 222 Model 37741 programmers by Benchmark Electronics more than one year prior to October 2, 2003 were not in "public use or on sale in this country, more than one year prior to the date of application for patent in the United States" under 35 U.S.C. § 102(b). That is, the Rule 132 Declaration establishes that the primary purpose of the manufacture of the 222 Model 37741 programmers was to conduct experimentation.

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<sup>3</sup> Office Action dated March 21, 2008 at p. 2, item 4.

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The Office Action states that "due to a lacking of evidence to the contrary,"<sup>4</sup> the claimed invention was in public use more than one year prior to the earliest effective filing date.<sup>5</sup> The Office Action found that because Medtronic confidential information was redacted from Exhibit A, "substantial necessary information providing for a date of drafting of the shown figure or the personal involvement of one or all of the listed inventors of the instant application in the drafting and conceptualization process" was also redacted.<sup>6</sup> Applicant respectfully submits that the Office Action appears to be applying an erroneous standard to determine whether the manufacture of the 222 Model 37741 programmers by Benchmark Electronics constitutes public use.

Applicant's Rule 132 Declaration should not be confused with an affidavit under 37 C.F.R. § 1.131 ("Rule 131 affidavit"). Applicant filed the Rule 132 Declaration to submit information pursuant to the duty to disclose information to patentability (37 C.F.R. § 1.56). In contrast, the purpose of a Rule 131 affidavit is to overcome a prior art rejection by proving invention of the claimed subject matter by the applicant prior to a particular date.<sup>7</sup> In a Rule 131 affidavit, the date of a drawing may be important to show completion of an invention prior to a particular date.<sup>8</sup>

The Office Action also erroneously applied a "diligence" standard to support the conclusion that the claimed invention was in public use more than one year prior to the earliest effective filing date. In particular, the Office Action stated that Exhibit C fails to show the "necessary robustness to show diligence." The Office Action further stated that:

[T]he redaction of an exact date on which the order with Benchmark Electronics was placed in each of the Exhibits makes it more difficult to estimate diligence, as an order date on 7 October 2002--the date of the first test--would be seen as a better potential showing of diligence than if the order had been placed at a substantially earlier date, e.g., 2001 or 2000.<sup>9</sup>

<sup>4</sup> Office Action dated March 21, 2008 at p. 4, item 4.

<sup>5</sup> *Id.*

<sup>6</sup> Office Action dated March 21, 2008 at p. 3, item 4.

<sup>7</sup> MPEP 2132.

<sup>8</sup> See MPEP 715.07.

<sup>9</sup> Office Action dated March 21, 2008 at p. 3, item 4.

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Neither "robustness" of diligence nor diligence per se are proper standards for determining whether the primary purpose of the manufacture of the Model 37741 programmers by Benchmark Electronics was to conduct experimentation. The Office Action appears to have misapplied the diligence inquiry relating to the sufficiency of a Rule 131 affidavit to Applicant's Rule 132 Declaration. Diligence of an applicant in reducing an invention to practice may be relevant in the context of a Rule 131 affidavit.<sup>10</sup> As established above, Applicant did not submit the Rule 132 Declaration to establish invention of the claimed subject matter prior to a particular date.

The Office Action also found that the Exhibits fail to show "any extent of rigorous scientific procedure and experimentation or successful results demonstrating significant and proven improvement over the art." However, a showing of experimental use by way of a 132 Declaration has no such requirement under the law.

The Office Action noted that 89 of the 222 programmers manufactured by Benchmark Electronics were used for experimental purposes.<sup>11</sup> The Office Action further stated that:

It is unclear what range of activities "internal use" [of the remainder of the 222 Model 37741 programmers] could encompass, e.g. whether the controllers [sic] provided to [Medtronic, Inc.] employees might have been allowed to leave secure facilities or to what extent said employees might be allowed to discuss or disclose the nature of the device in a public setting.<sup>12</sup>

The Rule 132 Declaration establishes that the remainder of the 222 Model 37741 programmers manufactured by Benchmark Electronics that were not used for tests reflected in Exhibits B and D were used internally by employees of Medtronic, Inc. This statement provided in the Rule 132 Declaration neither establishes that Medtronic, Inc. employees left secure facilities with a Model 37741 programmer nor that the employees discussed the Model 37741 programmers in a public setting. Thus, the Office Action's contention that the Model 37741 programmers manufactured by Benchmark Electronics may have been publicly used is mere conjecture.

Section 102(b) of the patent statute states that an invention described in a printed publication, in public use, or on sale more than one year prior to the date of application

<sup>10</sup> See MPEP 715.07(a).

<sup>11</sup> Office Action dated March 21, 2008 at pp. 3-4, item 4.

<sup>12</sup> Office Action dated March 21, 2008 at p. 4, item 4.

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constitutes a bar to patentability. Neither a Model 37741 programmer leaving "secure facilities" nor discussion or disclosure of the "nature" of the Model 37741 programmer in a "public setting" necessarily establish that Applicant's claimed invention was described in a printed publication, in public use or on sale. Furthermore, the Office Action does not provide any dates to establish that the alleged activities would have occurred more than one year prior to the date of application. Thus, the Office Action's allegation that the "internal use" referred to in the Rule 132 Declaration may constitute patent-barring activities is completely unsupported and insufficient to establish that the manufacture of the 222 Model 37741 programmers by Benchmark Electronics constitutes public use or a sale of the claimed invention.

The Office Action further found that the manufacture of the 222 Model 37741 programmers by Benchmark Electronics constitutes public use because "there is no evidence of a nondisclosure agreement on the parts of Medtronic, Inc. or Benchmark Electronics, Inc."<sup>13</sup> It is unclear how evidence of a nondisclosure agreement is related to an inquiry into whether the purpose of the request to manufacture the 222 Model 37741 programmers was to conduct experimentation.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 102(b).

#### **Claim Rejection Under 35 U.S.C. § 103**

In the final Office Action, claims 1-10, 11, 12, 14, 15, 17-21 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows et al. ((U.S. Patent No. 6,516,227, hereinafter referred to as Meadows)) in view of Whitehurst et al. (U.S. Patent Application Publication No. 2003/0229383, hereinafter referred to as Whitehurst). In addition, claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows in view of Whitehurst and further in view of Stanton et al. (U.S. Patent No. 6,249,703, hereinafter referred to as Stanton). Applicant respectfully traverses the rejection of the claims. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

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<sup>13</sup> *Id.*

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For example, the applied references fail to disclose or suggest a medical device programmer comprising an infrared interface to receive changes to software executed by a processor within the programmer during an infrared communication session, and a controller to activate the infrared interface to seek an infrared communication session for a finite period of time in response to power-up of the programmer, and deactivate the infrared interface after the finite period of time if the infrared communication session is not established, as recited by Applicant's independent claim 1.

In support of the rejection of claim 1, the Office Action acknowledged that Meadows does not disclose a finite seeking period or deactivation of the infrared interface after a finite period of time if the communication session is not established.<sup>14</sup> However, the Office Action cited Whitehurst as teaching these requirements and reasoned that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system taught by Meadows with the teachings of Whitehurst in order to minimize power consumption.<sup>15</sup> Applicant respectfully disagrees that Whitehurst cures the fundamental deficiencies in Meadows.

As an initial matter, it is unclear why one of ordinary skill in the art contemplating the teachings of Meadows would have even consulted Whitehurst. Whitehurst describes an implanted device with a radiofrequency (RF) telemetry receiver that allows communication with an external remote device. The RF telemetry receiver of the implanted device is periodically activated to conserve power consumption of the implanted device.<sup>16</sup> One of ordinary skill in the art looking to modify an infrared interface of an external medical device programmer as taught by Meadows would not have looked to an implanted medical device with an RF telemetry receiver as taught by Whitehurst.

As one example of the fundamental differences between an external medical device programmer and an implanted medical device as applied to Applicant's claimed invention, the medical device programmer provides a level of manual control that the implanted device of Whitehurst does not allow. For example, the handheld programmer of Meadows may be turned on and off through direct user activation.<sup>17</sup> In contrast, Whitehurst does not describe how the

<sup>14</sup> Office Action dated March 21, 2008 at p. 5, item 5.

<sup>15</sup> *Id.*

<sup>16</sup> Whitehurst at paragraph [0011].

<sup>17</sup> Meadows at col. 26, ll. 51-52.

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implanted device is powered on. The different degrees of control provided by a programmer compared to an implanted device result in different design criteria. Accordingly, it is unclear why one skilled in the art would have looked to Whitehurst to modify Meadows.

Additionally, even if the teachings of Meadows and Whitehurst were combined, the resulting combination would not meet each and every limitation of Applicant's independent claim 1. Whitehurst describes an RF communication technique for use between an implanted device and an external remote device. Thus, combining the teachings of Meadows and Whitehurst would result in an altered RF interface between the handheld programmer and implantable pulse generator described by Meadows. The infrared interface between the handheld programmer and the clinician programmer taught by Meadows would remain unchanged. Whitehurst fails to disclose or suggest that an RF interface or an infrared interface of the external remote device is activated for a finite seeking period or deactivated after a finite period of time if the communication session is not established.

Furthermore, the Office Action incorrectly characterized Applicant's claim 1 as requiring a finite communication session. More specifically, the Office Action addressed the limitation that "the infrared communication session is initiated for a finite amount of time."<sup>18</sup> However, Applicant's claim 1 requires that the infrared interface seeks an infrared communication session for a finite period of time.

The Office Action alleged that Meadows discloses that a telecommunicative link is established each time a stimulus parameter is changed or a charging session is initiated.<sup>19</sup> The Office Action also characterized turning off the handheld programmer after a period of disuse as a terminus of a finite infrared communication session. However, Applicant's claim 1 is not directed toward finite communication sessions but rather a finite seeking period to initiate a communication session. It seems that the Office Action as confused a finite communication period, per Meadows, with a finite seeking period as claimed. Even if the Meadows handheld programmer establishes multiple infrared communication sessions with a clinician programmer, the infrared interface of the handheld programmer may be continuously activated to listen for communication from (e.g., seek a communication session with) the clinician programmer.

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<sup>18</sup> Office Action dated March 21, 2008 at p. 5, item 5.

<sup>19</sup> *Id.* at pp. 5-6, item 5.

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The Meadows handheld programmer does not include a controller to deactivate an infrared interface if a communication session is not established after a finite period of time, as required by Applicant's claim 1. On the contrary, Meadows discloses multiple communication sessions having finite periods. The Office Action also stated that "since Meadows discloses multiple subsequent communication sessions, it is indeed inherent that not only is the duration of each session finite, but the duration of time between communications (i.e. the seeking period) is finite."<sup>20</sup> Yet, this statement does not reflect a proper understanding of the actual limitations set forth in Applicant's claims. Applicant disagrees with the Office Action's characterization of the duration of time between each telecommunicative link as a finite period of time for seeking an infrared communication session. The finite period of time set forth in claim 1 does not refer to the period of time between communication sessions, but rather the seeking of a communication session upon activation of the infrared interface. Even if multiple communication sessions are established in the Meadows system, the time between each of the sessions is not the pertinent issue. Again, the finite length limitation in claim 1 pertains to the limited listening period during which the infrared interface seeks a communication session.

With respect to the time periods between communication sessions, which the Office Action has characterized as seeking periods,<sup>21</sup> each of these time periods is terminated when a communication session is established, rather than if the communication session is not established. In fact, because Meadows teaches a system in which the handheld programmer and clinician's programmer, which communicate via infrared interfaces, are always properly synchronized<sup>22</sup>, an infrared communication session is likely sought until the communication session is established. This directly contradicts the requirements of Applicant's claim 1.

Applicant's claim 1 also requires that the infrared interface of a medical device programmer is activated to seek a communication session in response to power-up of the medical device programmer. The Office Action stated that it is an inherent property of the Meadows apparatus that the infrared communication session is initiated in response to power-up of the handheld programmer in order for the handheld programmer and the clinician programmer to be

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<sup>20</sup> *Id.* at p. 12, item 7.

<sup>21</sup> *Id.* at p. 12, item 7.

<sup>22</sup> Meadows at col. 17, ll. 61-65 and col. 36, ll. 24-28.

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appropriately synchronized.<sup>23</sup> Applicant respectfully disagrees with the Office Action's analysis of Meadows.

To support a finding of an inherent disclosure in Meadows, the Office Action must provide a basis in fact or technical reasoning to support that the allegedly inherent characteristic necessarily flows from the teachings of Meadows.<sup>24</sup> It is not an inherent feature of the Meadows apparatus that the infrared interface of the handheld programmer is activated upon power-up of the handheld programmer. For example, the infrared interface of the handheld programmer may be activated upon connection of the clinician programmer to allow proper synchronization with another programmer, which does not necessarily occur at power-up. Meadows discloses that the handheld programmer is selectively connected to a clinician programmer through an infrared serial port using an infrared cable extension.<sup>25</sup> Because the handheld programmer may be "selectively" connected to the clinician programmer<sup>26</sup>, the handheld programmer does not necessarily automatically seek a communication session with the clinician programmer in response to power up. For example, at times, the handheld programmer may communicate with the implantable pulse generator without the presence of the clinician programmer, while at other times, the clinician programmer may be connected to the handheld programmer to allow communication between the clinician programmer and implantable pulse generator.

In view of the Meadows disclosure, it is possible that the infrared interface of the Meadows handheld programmer is activated upon connection to the clinician programmer or at in other appropriate time, rather than in response to power-up of the handheld programmer. Accordingly, it does not necessarily flow from the teachings of Meadows that an infrared interface of a programmer that is activated to seek an infrared communication session in response to power-up of the programmer.

The Office Action also stated that interrogation of the implantable pulse generator in response to the activation of the hidden physician screen included on the handheld programmer constitutes seeking an infrared communication session for a finite period of time in response to

<sup>23</sup> Office Action dated March 21, 2008 at p. 7, item 4.

<sup>24</sup> *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

<sup>25</sup> Meadows at col. 31, ll. 41-43.

<sup>26</sup> See, e.g., claim 1 of Meadows.

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power-up of the programmer.<sup>27</sup> However, activation of the physician screen does not amount to a power-up of the programmer, as the Office Action contends. Meadows discloses that access to the hidden physician screen is made available through a specified coded button combination. The example Meadows provides is "pressing the IPG button 242 and the up/down buttons 244 and 245 simultaneously, followed by pressing a set sequence of the other buttons, e.g., pressing the SEL button 243 once, followed by the pressing the down button 245 twice."<sup>28</sup> In fact, Meadows specifically teaches that its handheld programmer is powered-on by simply pressing any button, not by activating a physician screen.<sup>29</sup> The physician screen is activated (and hence the subsequent interrogation of the implantable pulse generator occurs) only after a specified combination of buttons are pressed. Furthermore, it is unclear how interrogation of the implantable pulse generator via RF telemetry<sup>30</sup> relates to seeking an infrared communication session.

Whitehurst also fails to teach that the RF telemetry receiver of the implanted device is activated in response to power-up of the implanted device or the external remote device. As described above, Whitehurst does not teach or suggest how its implanted device may be powered on or off. The implanted RF telemetry receiver of the Whitehurst implanted device is activated based on defined time periods that are completely unrelated to a power-up of the programmer. Furthermore, the implanted device taught by Whitehurst does not appear to allow a user to control when the telemetry interface of the implanted medical device is activated.

With respect to claim 2 as amended, the applied references fail to disclose a finite time period of approximately 5 to 10 seconds following power-up to seek a communication session. The Office Action cited Whitehurst as teaching a finite seeking period and deactivation of the infrared interface after a finite period of time if the communication session is not established. However, Whitehurst describes a seeking period of 10 to 200 milliseconds, which is outside of the range of 5 to 10 seconds specified by claim 2.<sup>31</sup> Whitehurst teaches that, "the period of activation [of the RF telemetry system is] . . . sufficiently short so as to allow a reasonably

<sup>27</sup> Office Action dated March 21, 2008 at p. 12, item 7.

<sup>28</sup> Meadows at col. 38, ll. 22-32.

<sup>29</sup> *Id.* at col. 26, ll. 51-52.

<sup>30</sup> *Id.* at col. 23, ll. 48-50.

<sup>31</sup> Whitehurst at paragraph [0037].

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prompt response of the implant . . .<sup>32</sup> Given the vast difference between a 10 to 200 millisecond time range and a 5 to 10 second time range, Applicant submits Whitehurst does not teach or even suggest a 5 to 10 second listening period for its RF telemetry system, particularly in light of the power limitations<sup>33</sup> of an implanted device. Furthermore, nothing in the cited references provides a teaching or motivation for providing an infrared interface that seeks a communication session for a 5 to 10 second period of time.

In support of the rejection of claim 2, the Office Action cited paragraph 40 of Whitehurst as teaching a seeking time-out period of 10 seconds.<sup>34</sup> As described by Whitehurst at paragraph 40, the timeout period described by this passage of Whitehurst refers to a period of time elapsed after a command is received, rather than a finite period of time following power up of the device. After the timeout period, the implant switches from a receive mode with a 100 millisecond seeking period to a sleep-listen cycle with a shorter (e.g., 20 millisecond) seeking period.

Additionally, the Office Action reasoned that claims 2 and 20 are obvious because if the Meadows system remains in use for an hour or is always on, the IR interface is active for 5-10 seconds by nature of being on for longer than that.<sup>35</sup> The Office Action also reasoned that if the patient or clinician using the device powers down after 8 seconds, then the infrared interface has been active for 8 seconds, which satisfies the requirements of claim 2.<sup>36</sup> However, Applicant's claim 1 requires a controller that deactivates the infrared interface after the finite period of time if the infrared communication session is not established. The 5-10 seconds recited in claims 2 and 20 refer to a listening period for seeking a communication session, rather than the duration of the communication session itself. Therefore, an IR interface that is on for longer than 5-10 seconds does not meet the requirements of claim 2. Additionally, if a programmer is turned off after 8 seconds, the infrared interface is not necessarily seeking the communication session during that 8 seconds. Even if the infrared interface seeks the communications session during the 8 seconds the Meadows device is used, which Applicant disagrees with, the infrared interface is turned off

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<sup>32</sup> *Id.* at paragraph [0011].

<sup>33</sup> *Id.* at paragraph [0026].

<sup>34</sup> Office Action dated March 21, 2008 at p. 8, item 5.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

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regardless of whether or not a communication session is established and, therefore, fails to meet the requirements of claim 2.

With respect to claim 3, the applied references do not describe software changes comprising changes to an operating system of the programmer. The Office Action cited columns 16-17, lines 60-13 of Meadows as teaching this limitation.<sup>37</sup> However, this passage refers to operating program data sent to the implantable pulse generator rather than the programmer. Accordingly, Meadows fails to disclose or suggest a programmer including an infrared interface to receive software changes comprising changes to an operating system of the *programmer*.

The applied references fail to disclose or suggest a software loading port for loading the software upon assembly of the programmer, as recited by claim 6. The applied references also fail to disclose or suggest a plate member placed to cover the loading port, as further required by claim 8. In support of the rejection of claims 6 and 8, the Office Action stated that any electronic device comprising a housing of more than one part and containing software loaded on a memory inherently comprises a software loading port, where the port is considered to be the open portion of the housing in which the software-loaded circuitry is being inserted or affixed, and the other portion of the housing is considered to be the plate member covering the loading port.<sup>38</sup>

Applicant respectfully disagrees with the Office Action's interpretation of a "software loading port." Claim 6 requires the programmer to comprise a housing defining an aperture to provide access to the software loading port for loading software into memory. Thus, claim 6 clarifies that the software loading port is not the opening in a housing through which software-loaded circuitry is inserted into the housing. Instead, as fully supported by Applicant's specification, such as at paragraphs [0024] and [0110], the software loading port is an interface, accessible from outside the housing, to load software into memory. The housing of the programmer defines an aperture through which the software loading port, i.e., the interface, is accessible upon assembly of the programmer. The Office Action completely failed to address this requirement of claim 6.

As described in the present application, it may be advantageous for a programmer to include a software loading port for loading software upon assembly of the programmer. For

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<sup>37</sup> *Id.* at p. 7, item 5.

<sup>38</sup> *Id.*

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example, a plurality of generic programmers having common hardware components may be pre-manufactured and stored, and when a specific type of programmer is ordered, one of the generic programmers may be loaded with the appropriate software through the exposed loading port as one of the final steps in the manufacturing process<sup>39</sup>. The plate member is subsequently placed on the housing to cover the loading port, thereby blocking access to the loading port.

The Office Action reasoned that the "other portion of the housing" is considered to be a plate member. However, the Office Action offered no support for the conclusion that Meadows even includes two housing portions, or that one housing portion necessarily covers an open portion of another housing portion through which "software-loaded circuitry is being inserted or affixed." For at least these reasons, the cited art does not teach or suggest each of the elements of claims 6 and 8 or a motivation for modifying a medical device programmer to arrive at the invention defined by claims 6 and 8.

Applicant's claim 11 describes a first circuit board within the programmer housing, the first circuit board including telemetry circuitry, wherein the telemetry circuit is coupled to an antenna and a second circuit board within the programmer housing, the second circuit board including a display and display circuitry.

In support of the rejection of claim 11, the Office Action stated that it would have been an obvious matter of design choice to modify the Meadows system with two circuit boards to simplify manufacturing or reduce the size of the device.<sup>40</sup> The Office Action also reasoned that because cell phones incorporate a folding, two circuit board design that leaves a footprint half the size of an unfolded, one circuit board design, the two circuit board configuration would have been an obvious design choice to one of ordinary skill in the art.<sup>41</sup> Applicant respectfully disagrees with the Office Action's conclusions of obviousness.

Applicant's claim 11 recites a first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry. The Office Action has failed to address these requirements, and none of the cited references disclose or suggest such a configuration. As disclosed by the Applicant, the separation distance between the circuit boards may serve to reduce the effects of electrical and electromagnetic interference caused by the

<sup>39</sup> Applicant's disclosure at paragraphs [0024], [0025], and [0076].

<sup>40</sup> Office Action dated March 21, 2008 at p. 9, item 5.

<sup>41</sup> *Id.* at p. 13, item 7.

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display on signals transmitted and received by the internal antenna. In addition, the placement of the antenna and display electronics on different circuit boards may reduce electrical and electromagnetic interference.<sup>42</sup>

The Office Action reasoned that Lee provides support for the assertion that “less noise will arise between two components the further apart they are placed . . .”<sup>43</sup> However, Lee neither discloses a device including a first circuit board including telemetry circuitry nor a second circuit board including display and display circuitry, as recited by Applicant’s claim 11. Even if Lee teaches that “less noise will arise between two components the further apart they are placed . . .,” as the Office Action asserts, one skilled in the art would not have arrived at the invention of Applicant’s claim 11 based on the cited references. Nothing in Lee or the cited references teaches or suggests a programmer including first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry. Claims 12 and 14 depend from claim 11 and are also in condition for allowance for at least the reasons discussed with respect to claim 11.

Claim 15 recites an internal antenna defining an aperture and a battery bay extending at least partially into the aperture. The Office Action stated that it would have been an obvious matter of design choice to one of ordinary skill in the art to modify the system as taught by Meadows by extending the battery bay into the antenna aperture.<sup>44</sup> The Office Action referred to FIG. 25 of Causey, III et al. (U.S. Patent Application Publication No. 2002/002326, hereinafter “Causey”) and FIGS. 1A and 1B of Malek (U.S. Patent Application Publication No. 2003/0177031) as teaching this limitation.<sup>45</sup> Causey’s FIG. 25 illustrates computer 1006 in communication with communication station 1008, infusion device 1010, and RF programmer 1012. FIG. 25 of Causey does not illustrate an internal antenna or a battery bay, and certainly does not show a battery bay extending at least partially into an aperture defined by an internal antenna. FIGS. 1A and 1B of Malek also fail to show the claim limitations. Malek illustrates clinician’s programmer 102 including remote telemetry unit 240. Remote telemetry unit 240 fits into an aperture on the dorsal side of clinician’s programmer 102 and generally includes a

<sup>42</sup> Applicant’s disclosure at paragraph [0120].

<sup>43</sup> Office Action dated March 21, 2008 at p. 13, item 7.

<sup>44</sup> *Id.* at p. 9, item 4.

<sup>45</sup> *Id.* at p. 14, item 7.

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telemetry coil, receiver, transmitter, and telemetry processor. FIGS. 1A and 1B of Malek do not illustrate an internal antenna or a battery bay. The cited figures do not illustrate the limitations of claim 15 and, therefore, fail to disclose or suggest each and every element of claim 15.

Additionally, the Office Action stated that Applicant has not disclosed that positioning the batteries inside the aperture defined by the internal antenna provides an advantage, is used for a particular purpose, or solves a stated problem. Even if it were pertinent to the issue of obviousness, which Applicant disputes, it appears that the Office Action may have overlooked paragraph [0100] of Applicant's disclosure, which states positioning of a battery bay to extend at least partially into an aperture defined by the internal antenna can reduce external magnetic interference to the internal antenna by providing an RF load to the internal antenna, enhancing noise immunity.<sup>46</sup>

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-12, 14, 15-21 and 32 under 35 U.S.C. § 103(a). Reconsideration and withdrawal of this rejection is respectfully requested.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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By:

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<sup>46</sup> Applicant's disclosure at paragraph [0100].